UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	

PLAINTIFFS STATE OF NEVADA'S AND STATE OF MONTANA'S JOINT SUR-REPLY IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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I. INTRODUCTION

Defendants' replies suffer from four common defects. They (i) ignore controlling law; (ii) ignore controlling allegations of the States' amended complaints; (iii) continue to ignore the Court's May 13, 2003 Order that the States used as a guidepost in drafting those complaints; and (iv) assert a host of factual issues that are inappropriate at this stage of the proceedings.

A. The Court Should Sustain The States' Best Price Claims

Asserting federal preemption, defendants move to dismiss the States' Best Price claims. In doing so, defendants ignore the heavy burden that they are under to identify a compelling and actual conflict between the States' enforcement efforts and the Medicaid Act, yet defendants are unable to point to a viable conflict. *See Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75-76 (1st Cir. 2001) (the "strong medicine" of preemption within the jointly administered state-federal Medicaid Program is disfavored), *aff'd sub nom.*, 123 S. Ct. 1855 (2003). Congress explicitly chose to make the Medicaid Act jointly administered in an example of what the First Circuit terms "cooperative federalism." *Id.* at 75. An important component of this chosen construct was Congress's mandate that each participating state "conduct[] a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title . . . ." 42 U.S.C. § 1396b(q)(3). The Rebate Statute is a part of the Medicaid Act, and the Rebate Statute does not contain any words of preemption or even any suggestion that Congress reserved enforcement of the statute to the federal government. Thus, in pursuing their Best Price claims, the States are merely carrying out the duty that Congress assigned to them to pursue "***all*** aspects of fraud in connection with ***any*** aspect of the provision of medical assistance . . . ." *Id.* (emphasis added). The Best Price claims are not preempted.

Defendants next claim that the Best Price claims are not actionable under State Medicaid Fraud statutes, but defendants ignore the plain terms of those statutes. The Montana and Nevada Medicaid Fraud Acts were passed to remedy a very wide variety of potential frauds in connection with each State's respective Medicaid Program. The Montana statute applies to any information provided to determine "the amount of payment under the medicaid program . . . ." MONT. CODE ANN. § 53-6-160(1). Nevada's statute is similarly broad, defining "claim" as "a communication . . . which is used to identify specific goods . . . as reimbursable pursuant to the plan, or which states income or expense and is or may be used to determine a rate of payment pursuant to the plan." N.R.S. 422.470. Thus, notwithstanding defendants' unsupported effort to limit the scope of these statutes, both Acts apply to remedy misrepresented Best Prices and defendants' payment of rebates much lower than those rightfully due the States.

Defendants also maintain that the Montana False Claims Act cannot apply to purported misrepresentations made to the federal government. But defendants' overlook the fact that the rebate payments – which themselves constitute misrepresentations – are made by defendants directly to Montana. In any event, defendants also ignore the plain wording of the Montana FCA, which applies to misrepresentations made indirectly that cause false claims to be made, Mont. Code Ann. § 17-8-231, which is very similar to the prohibitions found in the federal act and which this Court previously found to apply broadly to all types of fraud that might result in financial loss to the government. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 50-51 (D. Mass. 2001).

Lastly, defendants assert that the Best Price claims are not pled with sufficient particularity, yet the States have "allege[d] the circumstances of the fraud" and provided sufficient examples of those circumstances as required. *See Parke-Davis*, 147 F. Supp. 2d at 46. The States are simply "***not*** required to plead ***all*** of the evidence or facts supporting" their fraud theory. *Id.* at 46-47 (emphasis added). Furthermore, several defendants have already paid

substantial sums of money to settle Best Price claims, and some have even entered ***criminal*** guilty pleas.

B. The Court Should Sustain The States' AWP Claims

Defendants urge dismissal of the States' AWP claims on the basis that each State was aware of the complex frauds that defendants committed. Defendants' assertion runs directly counter to the myriad allegations found in the States' complaints regarding fraudulent concealment and the fact that neither State was aware of the fraud. Furthermore, defendants' argument is indeed curious given that several of their internal documents recognize that selling the spread was wrongful; that the OIG recently issued guidelines stating that the government sets reimbursement with the expectation that defendants provide complete and accurate data; that so many defendants have recently pled guilty to felony violations; and that the Congress was shocked to recently learn about examples of fraud. In any event, defendants merely invoke factual issues that cannot be determined here on a motion to dismiss.

Defendants argue for dismissal of Nevada's RICO claim on the basis that Nevada is not a "person" under Nevada RICO for purposes of pursuing a damage remedy, and that Nevada fails to plead viable Manufacturer-Publisher enterprises. Both arguments fail. N.R.S. § 193.010 provides that "the words and terms defined in [Nevada's criminal code] have the meaning ascribed to them in those sections," and N.R.S. § 193.0205 defines "person" to include the State of Nevada. As to defendants' challenge to the enterprises, Nevada's complaint, drafted with the benefit of the Court's May 13 Order, solves the Court's "hub and spoke" concern. Further, it adds detailed factual allegations that explain the structure of the enterprises and identify a shared common purpose, to wit, to make more money. Defendant's financial purpose is to "push the spread" and perpetuate the AWP Inflation Scheme. NC ¶ 449. The Publishers, too, have a financial interest in blindly accepting the AWPs reported by defendants. If they did not, defendants, who are under no obligation to provide the AWPs to the Publishers, could simply report to the AWPs to others, which would cause the Publishers to spend money to extensively

survey actual sales prices in the market. NC ¶ 449. These factual allegations, and more, directly address the Court's concerns regarding common purpose and participation in an enterprise. Though defendants call these allegations "ritualistic," they are in fact the type of factual allegations that satisfy RICO pleading standards in this Circuit, particularly where the facts are exclusively in defendants' possession.

C. The Court Should Reject Defendants' So-Called "Defendant-Specific"Arguments

Much of the arguments advanced in the defendant-specific briefing are in fact common arguments. For example, defendants repeatedly assert that there is no incentive to engage in the AWP Inflation Scheme in the generic and multiple source drug market. However, the complaints' controlling allegations expressly aver the reasons why AWP inflation occurs for generic and multiple source drugs and provides specific allegations that AWP inflation in the generic marketplace is rampant; cites specific instances where generic drug manufacturers have acted to meet the AWP inflated prices of others who inflate their AWPs; and alleges that one manufacturer has admitted in litigation elsewhere that it competes with other defendants on the basis of AWP inflation – including a specific recognition of the importance of reimbursement policies within Medicaid – and, when prevented from doing so, immediately lost business. Thus, the States establish that the AWP Inflation Scheme involves generic and multiple source manufacturers.

Another common tactic in defendants' motions is to raise the pleading bar by demanding specifics not required by Rule 9(b) or this Court's May 13 Order. To reiterate, the States crafted their amended complaints to comply with the Court's May 13 Order calling for the pleading of specific drugs and AWPs. Unsatisfied, defendants demand that the States list specific instances of fraud in connection with ***each*** specific drug, but this was not required in the Court's May 13 Order. Nor do controlling authorities require such an impossible level of detail. The complaint need only allege the "circumstances of the fraud" and "the general outline of the general scheme to defraud." *See Parke-Davis*, 147 F. Supp. 2d at 46; *Kuney Int'l, S.A. v. DiIanni*, 746 F. Supp.

234, 237 (D. Mass. 1990). The States do this, and then they provide specific examples for many of the drugs at issue. It is not necessary for the States to plead specifics for every drug and, in fact, the States could not because this information is in defendants' exclusive possession. *See Parke-Davis*, 147 F. Supp. 2d at 49 (where the Court recognized that "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible").

* * * *

This sur-reply memorandum is divided into three primary sections as follows: Section II addresses defendants' efforts to obtain dismissal of the State's Best Price Claims; Section III rebuts defendants' arguments regarding the AWP claims; and Section IV addresses the defendant-specific arguments found in defendants' separate reply briefing. Taken as a whole, these sections, along with the arguments appearing in the States' joint opposition brief, demonstrate that defendants' motions should be dismissed in their entirety.

II. THE BEST PRICE CLAIMS SHOULD BE SUSTAINED

A. The Medicaid Rebate Statute Does Not Preempt The Best Price Claims

No court has ever read the Federal Medicaid Act as preventing a State from seeking a remedy for Medicaid fraud, and defendants fail to present a cogent argument as to why this Court should be the first to do so. The Medicaid Act requires that each participating state "conduct[] a statewide program for the investigation and prosecution of violations of ***all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title*** . . . ." 42 U.S.C. § 1396b(q)(3) (emphasis added).[1] The Rebate Program, which is an integral aspect of the overall Medicaid Program, has the purpose of

[1] *See also* 42 U.S.C. § 1396a(61) ("A State plan for medical assistance ***must*** . . . provide that the State must demonstrate that it operates a Medicaid fraud and abuse control unit described in section 1903(q) [42 U.S.C. § 1396b(q)] that effectively carries out the functions and requirements described in such section, ...") (emphasis added); 42 U.S.C. § 1396a(25) (state must "take all reasonable measures to ascertain the legal liability of third parties" and pursue reimbursement).

"reduc[ing] the cost of Medicaid and . . . prevent[ing] pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs." *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001).

The States' Best Price claims merely carry out Congress's mandate that each state enforce state law to combat "any and all aspects of fraud in connection with . . . any aspect" of the Medicaid Program. Moreover, Montana's and Nevada's Best Price claims are entirely consistent with the Rebate Statute's twin objectives of reducing the cost of Medicaid and ensuring that the States are not charged above-market prices for drugs. These claims simply cannot reasonably be interpreted in any other manner.

Nonetheless, in reply Defendants conjure a sort of "bright line" rule under which states are free to pursue enforcement actions limited to "eligibility and covered services," Defs. Reply at 1, but are prohibited from acting on any issues relating to rebates. Hence, defendants coin the Rebate Statute a "unique aspect of the Medicaid program" that the States purportedly "have no discretion" to enforce. Defs. Reply at 1. Defendants are unable to cite to a section or clause of the Rebate Statute providing that the States are powerless to enforce rebate obligations, and defendants fail to cite a single case that supports their novel reading. Congress did ***not*** expressly reserve to the federal government the ability to enforce the Rebate Statute, and this omission speaks volumes given that (i) Congress provided for a jointly administered Medicaid Program, and (ii) courts, including the First Circuit, have long recognized that Medicaid was an example of "cooperative federalism" "[w]here coordinated state and federal efforts exist within a complementary administrative framework" for "the pursuit of common purposes." *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001), *aff'd sub nom.*, 123 S. Ct. 1855 (2003). Therefore, there is simply no evidence that Congress intended to treat the rebate scheme any differently.

In light of this backdrop, courts will ***not*** invoke the "strong medicine" of preemption absent a compelling argument of actual conflict. *Id.* at 76. Here, no actual conflict exists

between the States' enforcement efforts and the terms or purpose of the Rebate Statute. With regard to the remedial provisions of the Statute, which are found at 42 U.S.C. § 1396r-8(b)(1)(A)(3)(C), they do not provide that the Secretary of HHS has the exclusive authority to take enforcement action as defendants would have the Court believe. Indeed, section (3)(C)(ii), addressing the submission of false information by a drug manufacturer, provides that a manufacturer can be liable for a civil penalty up to $100,000 for each item of false information submitted, but does not even mention the Secretary – let alone suggest that only the Secretary is authorized to pursue the penalties.[2] Furthermore, this section does not expressly address a state's authority to employ state law in enforcing rebate obligations, but quite strongly suggests through a reservations clause that other enforcement efforts, including those by the states, are authorized without limitation: "Such civil money penalties are in addition to other penalties as may be prescribed by law."[3]

Although defendants fail to cite ***any*** cases preempting state law enforcement efforts under the Rebate Statute, defendants criticize the States' reliance on *Concannon* on the basis that *Concannon* did not involve preemption under the Rebate Statute. Importantly, and as defendants fail to acknowledge, the First Circuit took a very ***narrow*** view of preemption under the Medicaid Act, of which the Rebate Statute itself is a part. Indeed, the Rebate Statute was codified in the section of the Medicaid Act titled "[p]ayment for covered outpatient drugs" generally and not in

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[2] Defendants claim that the Secretary has sole authority to enforce penalties, but the only section of the Rebate Statute that expressly states that the "***Secretary*** may impose a civil monetary penalty" is Section (3)(B) which addresses potential refusals by manufacturers and others to participate in price surveys that the Secretary may conduct. (Emphasis added.) An interesting contrast is found in Section (3)(C) pertaining to penalties for the provision of false information, where Congress chose not to provide that the Secretary in specific can impose penalties; instead, the section constitutes a general grant of liability: "Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information."

[3] Defendants argue in a footnote that this reservations clause is limited by the text following it in a separate sentence, which provides for a remedy under the Civil Monetary Penalties and Assessment Act codified at 42 U.S.C. § 1320a-7a. Defs. Reply at 3 n.1. Such an interpretation is untenable, as it runs counter to Congress's choice to use the general phrase "as may be prescribed by law." If defendants' interpretation were correct, Congress would surely have written the reservations clause in a limiting manner by specifically referencing only those laws that could provide additional remedies. In other words, under defendants' view, the section would state as follows: "Such civil money penalties are in addition to other penalties as may be prescribed by 42 U.S.C. § 1320a-7a." But Congress did not write the Statute in this manner, choosing instead to make the reservations clause applicable to all "law."

some stand-alone section of the United States Code such that an inference can be drawn that the Statute escapes the very narrow approach that courts have taken in evaluating preemption issues under the Medicaid Act. In the absence of an appellate court decision addressing the precise issue of whether the Rebate Statute preempts state efforts to enforce it – especially given the express federalist foundation of the entire Medicaid Program – *Concannon* remains the most persuasive authority on the preemption question here.

Defendants' continuing attempt to apply *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), is unavailing. Pivotal to the court's decision in *Buckman* was its observation that the plaintiffs' claims would upset FDA enforcement options. *Id.* at 349-50. Defendants can point to no similar conflict here, especially when the Medicaid Act contemplates concurrent state and federal enforcement of its provisions. Unlike the FDA Act at issue in *Buckman*, Congress did not intend for the Medicaid Act generally, or the Rebate Statute more specifically, to be enforced exclusively by the Federal Government. *See id.* at 352. Because Congress created this concurrent enforcement regime for the Medicaid Act generally, it would surely have expressly provided that the Rebate Act preempted state law remedies had Congress intended such a result. But it did not.

Nor can defendants distinguish this Court's prior rejection of *Buckman*, *see In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 189 (D. Mass. 2003) ("*AWP*"), on the basis that defendants report Best Prices directly to the federal government. The Court's recognition that "the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs' harm" (*id.*), still holds true here. This is particularly manifest given the fact that ***all*** of the rebates are paid directly to the states; the federal government does ***not*** share in any rebates.[4]

[4] Defendants also proclaim that the States "have no answer to the Medicaid rebate preemption cases" cited by defendants. Defs. Reply at 8 & n.2. But as the States pointed out in their opposition memorandum, those cases are inapposite because they were based on conflicts with reimbursements set by the Rebate Statute; no such conflict exists here. *See* Joint Opp. Br. at 7-8.

That the Court will be evaluating the Rebate Statute's definition of "Best Price," *see* 42 U.S.C. § 1396r-8(c)(1)(C), does not support a finding of preemption. Interpreting provisions of the Rebate Statute will be no different than interpreting other provisions of the Medicaid Act. Indeed, this Court has already recognized that "state courts frequently construe terms in federal laws in order to adjudicate causes of action based in state law, and the Supreme Court [remains] the ultimate decision-maker on federal questions arising out of state court." *AWP*, 263 F. Supp. 2d at 188-89.

Federal preemption of state law within the jointly administered state-federal Medicaid Program is disfavored. *Concannon*, 249 F.3d at 75. Defendants have the burden of demonstrating that, in amending the Medicaid Act to include the Rebate Statute, Congress's "clear and manifest purpose" was to preempt any attempts by states to enforce the Rebate Statute. *See id.; see also AWP*, 263 F. Supp. 2d at 188 ("A conflict exists when it is impossible to comply with both state and federal law, or if the state law is an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the federal legislation.") (quoting *Pennsylvania Medical Soc. v. Marconis*, 942 F.2d 842, 848 (3d Cir. 1991)). Defendants have failed to satisfy this burden.

B. The Best Price Claims Are Valid Causes Of Action Under The Medicaid Fraud Statutes

In asserting that the Montana and Nevada Medicaid Fraud Acts do not apply to their wrongful conduct in misrepresenting Best Prices, defendants ignore the plain language of the statutes and the wide net that the statutes employ to catch and remedy all frauds associated with payments made by the States under their plans. As the States explained in their joint opposition brief, MONT. CODE ANN. § 53-6-160(1) applies to information provided to determine "the amount of payment under the medicaid program . . . ." Nevada's statute is similarly broad, defining "claim" as "a communication . . . which is used to identify specific goods . . . as reimbursable pursuant to the plan, or which states income or expense and is or may be used to

determine a rate of payment pursuant to the plan." N.R.S. 422.470; *see also* N.R.S. 422.525(1) (defining "statement or representation" as used in N.R.S. 422.540(1)(b) and (d) to include "a report, claim, certification, acknowledgment or ratification of . . . [f]inancial information.").[5] *See also* Joint Opp. Br. at 8-11.

Defendants play word games, attempting to differentiate the concept of "cost" from "payments" made by the States. Defs. Reply at 9-10. In defendants' view, therefore, the statutes apply only to the discrete payments that the States make for the drugs. But defendants' Best Prices and the rebates that defendants pay to the States are "payments" within the purview of the Nevada and Montana Medicaid Fraud statutes: defendants cannot deny that each State Medicaid Program makes payments for defendants' drugs, and that those payments, ***coupled with the rebates that defendants pay directly to the States***, constitute the "net" payment for defendants' products. Thus, in Montana, the rebates are used to determine "the amount of payment under the medicaid program . . . ." MONT. CODE ANN. § 53-6-160(1). And in Nevada, the Best Price reporting and the payment of rebates constitute "a communication . . . which is used to identify specific goods . . . as reimbursable pursuant to the plan, or which states income or expense and is or may be used to determine a rate of payment pursuant to the plan." N.R.S. 422.470

Not only does defendants' reading run counter to the plain terms of these statutes, defendants' interpretation derogates the careful steps that the Montana and Nevada legislatures took to ensure that their respective Medicaid Fraud Acts are broadly construed. *See, e.g.*, N.R.S. 422.540(1)(a)-(d) (extending prohibitions beyond person making false claim or representation to those who cause them to be made); MONT. CODE ANN. § 53-6-160 (extending liability for false statements made indirectly). Defendants simply cannot be immune under these statutes from liability for the frauds that they have perpetrated in the Best Price arena.

[5] Defendants continue to assert that N.R.S. 422.540(1)(b) and (d) do not apply to them, *see* Defs. Reply at 10 n.3, yet defendants failed to rebut Nevada's explanation that defendants are indeed providers of goods to the Nevada Medicaid Program. *See* Joint. Opp. Br. at 9.

C. Montana States A Claim For Violation Of The False Claims Act

In its opposition brief, Montana explained that the Montana False Claims Act, like the Federal FCA, reaches those who indirectly cause false claims to be submitted to the government. Joint Opp. Br. at 11-14. In response, defendants seek to exploit a difference between the Montana False Claims Act and the Federal FCA by stating that the Federal FCA, unlike the Montana FCA, applies to efforts to conceal. Defs. Reply at 10-11 (citing 31 U.S.C. § 3729(a)(7)). But this difference is immaterial to the inquiry at hand. Significantly, this Court did not rely on the language cited by defendants in rendering its decision in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), where the Court held that defendants could be liable for inducing physicians to submit false claims. Instead, the Court highlighted the FCA's provision of liability for one who "knowingly makes, uses, or ***causes to be made*** or used" a false statement. 147 F. Supp. 2d at 50 (quoting 31 U.S.C. § 3729(a)) (emphasis supplied by the Court). The Montana FCA likewise imposes liability on one who presents or "***causes to be presented***" a false claim. MONT. CODE ANN. § 17-8-231 (emphasis added). This demonstrates that, although the Montana FCA and the Federal FCA may differ in some respects, they are nearly identical on the most important inquiry to be made here, to wit, they ***both*** capture and prohibit false claims made indirectly through others.

Defendants make the same argument with respect to the Illinois False Claims Act, yet the Illinois statute also extends liability to those who "***cause[] to be made*** or used a false record or statement . . . ." 740 ILCS 175/3(a)(2) (emphasis added). Tellingly, defendants do not attempt to distinguish Montana's reliance on *People ex rel. Levenstein v. Salafsky*, 2003 Ill. App. Lexis 560, at *15-16 (Ill. App. Ct. May 5, 2003), and *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 738 (D.C. Cir. 1998), in any other manner, because they cannot. Defendants likewise are unable to argue against application of the federal definition of "claim" to the Montana False Claims Act and this Court's recognition that the word "claim" is to be broadly

construed to all types of fraud that might result in financial loss to the government. *See Parke-Davis*, 147 F. Supp. 2d at 50-51.

In sum, the rebates paid directly by defendants to Montana constitute representations of the amount owed under the Rebate Statute, and if rebates are too small because defendants falsely report Best Prices, defendants have made a "false, fictitious, or fraudulent claim for allowance or payment to [a] state agency." MONT. CODE ANN. § 17-8-231 Alternatively, the Best Prices reported to CMS were false claims that caused the Medicaid Program to pay more than it otherwise would have for drugs. Hence, and as Montana alleges, misrepresenting Best Prices had the "foreseeable" and "intended consequence" of depriving Montana of full rebates owed. *See Parke-Davis*, 147 F. Supp. 2d at 52-53. Defendants simply cannot successfully argue that there is no nexus between misrepresenting Best Prices to CMS and the associated deprivation of monies owed to Montana.

D. The Best Price Allegations Properly State Claims

Notwithstanding the States' myriad allegations of fraudulent Best Price reporting, defendants continue to maintain that Rule 9(b) has not been satisfied. Defs. Reply at 11-12. Defendants again ignore this Court's decision in *Parke-Davis*, holding that where a complaint has "allege[d] the circumstances of the fraud," it is "***not*** required to plead ***all*** of the evidence or facts supporting it." *Id.* at 46-47 (emphasis added); *see also id.* at 46 ("The requirements of Rule 9(b) . . . must be read in conjunction with Fed. R. Civ. P. 8(a)," which requires only a "short and plain statement of the claim."). Indeed, the Court has recognized that "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible." *Id.* at 49.

The complaints provide a "general outline of the general scheme to defraud." In keeping with their artificial price inflation scheme, each defendant did not report the actual Best Price, but instead reported higher prices that excluded discounts and other inducements offered to physicians, such as free goods, volume discounts, rebates, educational grants and other programs

that lower the providers' actual cost of the drugs. Consequently, defendants paid rebates lower than those actually due had defendants accurately reported Best Prices. NC ¶ 392; MC ¶ 612. The complaints then provide details supporting this general outline. *See, e.g.*, MC ¶¶ 181-84, 244; NC ¶¶ 144-47, 189 (Amgen hidden rebates), MC ¶ 310 (Baxter providing free goods), MC ¶¶ 320-22 (Bayer providing free goods); MC ¶ 36; NC ¶ 270 (B. Braun offering educational grants or other value); MC ¶ 402 (Dey offering free goods); MC ¶¶ 434, 459 (GSK providing rebates); MC ¶ 476; NC ¶ 297 (Immunex providing free samples); MC ¶ 510; NC ¶ 331 (Pfizer providing unrestricted educational grants); MC ¶ 518, 523-24 (Pharmacia providing free goods); MC ¶ 544; NC ¶ 345 (Schering providing drug samples); MC ¶¶ 565; NC ¶ 336 (Sicor Group providing free goods); MC ¶¶ 578-81 (TAP using credit memos, free goods); MC ¶ 599; NC ¶ 379 (Watson discounts).

Importantly, defendants GSK, Bayer, AstraZeneca, Pfizer and TAP have all been caught "red handed" manipulating their Best Price reporting, leading to substantial settlements and even some ***criminal*** pleas summarized as follows:

Defendant	Drugs	Settlement	Citation
GSK	Flonase Paxil	$87,600,922	MC ¶¶ 617-20
Bayer	Cipro Adalat CC	$242 million civil damages and penalties $5,590,800 criminal fine ***Guilty plea*** to a felony violation of the Prescription Drug Marketing Act	MC ¶¶ 621-27
AstraZeneca	Zoladex	$355 million in criminal penalties and civil damages and penalties ***Guilty plea***	MC ¶¶ 628-30 NC ¶¶ 398-400
Pfizer	Lipitor	$49 million	MC ¶¶ 631-34 NC ¶¶ 401-03
TAP	Lupron	$25,516,440 to states ***Guilty plea*** to conspiracy to	MC ¶ 583

		violate the Prescription Drug Marketing Act	

These settlements and guilty pleas provide even more weight to the States' claims of Best Price fraud.

The States' Best Price allegations go far beyond putting defendants on notice of the claims against them, and nothing more is required per *Parke-Davis*.

III. THE AWP CLAIMS SHOULD BE SUSTAINED

A. Defendants' "Government Knowledge" Contentions Provide No Basis For Dismissing The AWP Claims

Acknowledging that estoppel will not apply to bar the States' claims, defendants maintain that Montana and Nevada could not possibly have been deceived or defrauded because both states purportedly were aware of defendants' manipulations. Defs. Reply at 12.[6] But this is just a "back-door" manner of asserting estoppel and should not be countenanced. The Court should see through this ruse and reject defendants' "government knowledge" defense on this basis alone.

But there are other reasons for rejecting the defense, reasons that defendants did not even make the effort to rebut in their reply brief. Defendants' entire "government knowledge" construct is not only false, it also runs counter to the ***controlling*** allegations in the complaints that outline how defendants prevented the States from knowing the actual pricing structures for the drugs. Examples are as follows:

- Defendants knew that they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. Defendants also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret. [MC ¶ 169; NC ¶ 132.]

- Each defendant concealed its fraudulent conduct from the State[s] and others by controlling the process by which the AWPs for drugs were set. Defendants

[6] Several defendants also raise this argument in their so-called defendant-"specific" replies. *See, e.g.*, Abbott Reply at 2-3.

> prevented the State[s] and others from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, defendants' fraudulent conduct was of such a nature as to be self-concealing. [MC ¶ 635; NC ¶ 404.]

- Each defendant closely guarded its pricing structures and marketing plans from public disclosure. For example, a recent CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39. [MC ¶ 636; NC ¶ 405.]

- Each defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for drugs. [MC ¶ 637; NC ¶ 406.]

- [E]ach defendant concealed that (i) its AWPs were highly-inflated (and were inflated to cause the [State] Medicaid Program and other reimbursement programs and Patients making co-pays to overpay for drugs); (ii) it was manipulating the AWPs of the drugs; (iii) its inflated AWPs greatly exceeded the average of the wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to the defendant in conducting its ordinary business affairs; and (iv) it was not reporting true Best Prices and paying the full rebates due Medicaid. [MC ¶ 640; NC ¶ 409.]

- [The States] w[ere] diligent in pursuing an investigation of the claims asserted [and] [t]hrough no fault of [their] own, [the States] did not receive inquiry notice nor learn of the factual basis for [their] claims in this Complaint and the injuries suffered therefrom until recently. . . . Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. [The States] ha[ve] been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on [their] part. The State[s] could not reasonably have discovered the fraudulent nature of the published AWPs and Best Prices. [MC ¶¶ 641-42; NC ¶¶ 410-11.]

Moreover, if state officials were indeed aware of defendants' misdeeds, it is rather curious – and certainly an issue for later factual determination – as to why some defendants internally recognized that AWP inflation was improper. For instance, Aventis decried "SELLING AGAINST AWP:"

> At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of any manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.